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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|----------------------------|-------------|----------------------|---------------------|------------------|
| 10/035,319 | 10/26/2001 | Michael R.S. Hill | P-10124.00 | 3335 |
| 27581 | 7590 | 12/28/2004 | | |
| MEDTRONIC, INC. | | | EXAMINER | |
| 710 MEDTRONIC PARKWAY NE | | | OROPEZA, FRANCES P | |
| MS-LC340 | | | | |
| MINNEAPOLIS, MN 55432-5604 | | | ART UNIT | PAPER NUMBER |
| | | | 3762 | |

DATE MAILED: 12/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|--------------------|--------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/035,319 | HILL ET AL. |
| | Examiner | Art Unit |
| | Frances P. Orosepa | 3762 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 10/12/04 (Election).
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-36 is/are pending in the application.
 4a) Of the above claim(s) 1-19 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 20-36 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 30 April 2003 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date 2/15/02 & 10/15/02.

4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.
 5) Notice of Informal Patent Application (PTO-152)
 6) Other: _____.

DETAILED ACTION

Election/ Restriction

1. Claims 1-19 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 10/12/04.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 20, 22-24, 26-28 and 31-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Holmstrom et al. (EP 0 688 577 A1). Holmstrom et al. disclose a device for impending supraventricular heart therapy comprising an implantable cardiac and neural electrode system to sense and stimulate (23), a detection block (5) of cardiac (51) and neural (53) sensing circuits to sense the physiological parameter(s), a neural stimulation circuit (9), a control circuit (13), and a pacing circuit (7) (figure 1). The therapy is provided for impending ventricular tachyarrhythmias, hence the system anticipates the occurrence of a cardiac insult. The neural generator includes a time control unit (92) that is programmed, hence the device is capable or teaches neural stimulation prior to onset of the insult, for a period to time after the onset of the

insult, or for a time period after termination of the insult. The stimulator can be used externally with external and internal electrodes, read as positioned proximate an external body surface and positioned subcutaneously, respectively (abstract; figure 1; col. 3 @ 6-27 and 37-50; col. 4 @ 1-50; col. 5 @ 10-39; col. 7 @ 43-52; col. 8 @ 10-56; col. 9 @ 10-13 and 40-44).

4. Claims 20, 22-24, 26 and 29-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Hartlaub (US 6134470). Hartlaub discloses a method and device with physiological sensors (342), sensor controls (340), neural stimulator (272) and controllers (270, 244) to detect the precursors to tachyarrhythmias and respond with stimulation of the spinal cord/ spinal roots, pacing therapy and/or a drug delivery system. The therapy is provided for the precursors to tachyarrhythmias, hence the system anticipates the occurrence of a cardiac insult. The spinal cord generator is activated for predetermined time periods, hence the device is capable or teaches neural stimulation prior to onset of the insult, for a period to time after the onset of the insult, or for a time period after termination of the insult. The results of past stimulation are used to perform future stimulation (abstract; figures 1, 2; col. 1 @ 42-52; col. 2 @ 3-15 and 40-53; col. 4 @ 35-47; col. 4 @ 56 – col. 5 @ 7; col. 6 @ 25-54 col. 7 @ 47-61; col. 8 @ 66 – col. 9 @ 20; col. 9 @ 53-67; col. 11 @ 24-65; col. 12 @ 19-25; col. 13 @ 4-34).

5. Claims 20-22, 26, 31, 32 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Obel et al. (US 5199428). Obel et al. disclose a nerve stimulator (108) and pacing therapy (104) to respond to a physiological parameter (pH and SO2) which provides “a meaningful predictor of ischemia” and potential arrhythmias to the controller (100). The therapy is provided

for “a meaningful predictor of ischemia” and potential arrhythmias, hence the system anticipates the occurrence of a cardiac insult. A patient activation mechanism is taught (abstract; figure 2; col. 5 @ 25-51; col. 6 @ 39-53; col. 7 @ 5-25; col. 10 @ 3-5).

6. Claims 20, 22-26, 31, 32 and 36 are rejected under 35 U.S.C. 102(e) as being anticipated by Sweeney et al. (US 6272377). Sweeney et al. disclose a cardiac management system that predicts arrhythmias, based on physiological parameter(s), and treats the anticipated occurrence of a cardiac insult with neural stimulation. A warning is provided to the patient that an arrhythmia has been predicted (abstract; col. 1 @ 7-11; col. 2 @ 11-16, 39-45 and 58-66; col. 4 @ 61 – col. 5 @ 20; col. 8 @ 23-55; col. 9 @ 3-32 and 45-62).

Drawings

7. Figure 6F is objected to because --symptoms-- in block 560 is misspelled.

Specification

8. The “Related Cases” information on page 1 of the specification needs to be updated.
9. On page 16 under “Blood Chemistry”, --Glucose-- is misspelled.

Abstract

10. The abstract of the disclosure is objected to because the invention being prosecuted is not described in the abstract, the prosecuted invention does not determine the effectiveness or efficacy of the stimulation, but rather controls the stimulation circuit based on the anticipation of

an occurrence of a cardiac insult as indicated by at least one physiological parameter.

Correction is required. See MPEP § 608.01(b).

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frances P. Oropeza whose telephone number is (571) 272-4953. The examiner can normally be reached Monday through Friday from 9 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes, can be reached on (571) 272-4955. The telephone number for facsimiles for regular communication and After Final communications is (703) 872-9306.

Frances P. Oropeza
Patent Examiner
Art Unit 3762

3/0
12/14/04



ANGELA D. SYKES
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700